

Christophe P.G. Gerald, et al.

Serial No.: 09/866,248

Filed: May 25, 2001

Page 11

REMARKS

Claims 183-191 are pending in the subject application. By this amendment, applicants have amended the specification to update the continuing data and claims 183 to 191. Accordingly, upon entry of this Amendment, claims 183-191, as amended, will be pending and under examination.

Applicants maintain that the amendments to the claims raise no issue of new matter. Support for the amendments to claims 183, 184, 190 and 191, may be found inter alia in the specification as originally filed on page 1, line 29-36; page 29, line 6-13; and page 82, line 24 through page 83, line 3. In addition, numerous examples are given regarding receptor activation assays. Specific examples include, Cyclic AMP (cAMP) Formation Assay (page 83, lines 5-19); Arachidonic Acid Release Assay (page 83, lines 21 through page 84, line 4); GTP γ S Functional Assay (page 85, lines 29 through page 86, line 21) and MAP Kinase Assay (page 86, line 23 through page 87, line 1). Support for the amendments to claim 186, may be found inter alia in the specification as originally filed on page 12, line 33 through page 13, line 13; page 13, line 15-30; page 48, line 28 through page 49, line 8; and page 49, lines 10-25. Accordingly, Applicants respectfully request entry of this Amendment.

The undersigned wishes to thank Examiner Murphy for the courtesy extended during the August 18, 2005 Examiner Interview. During the August 18, 2005 interview, the aforementioned claim amendments were discussed and the Examiner acknowledged that such amendments would obviate the outstanding rejections.

Rejection Under 35 USC § 112, First Paragraph

On page 2 of the March 24, 2005 Office Action, the Examiner rejected claims 183-191

Christophe P.G. Gerald, et al.
Serial No.: 09/866,248
Filed: May 25, 2001
Page 12

under 35 USC 112, first paragraph. The Examiner alleged that while the specification is enabling for methods of preparation of compositions which are agonists or antagonists of the mammalian NPFF receptor of SEQ ID NO: 6, wherein the compound causes an increase (or decrease) in the level of inward chloride current or inositol phosphate release, the specification does not reasonably provide enablement for methods of preparation of compositions which are agonists or antagonists of the mammalian NPFF receptor of SEQ ID NO: 6 wherein the compound causes an increase (or decrease) of NPFF receptor activity. The Examiner further alleged that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Examiner acknowledged that the specification teaches methods of preparation of compositions which are agonists or antagonists of the mammalian NPFF receptor in SEQ ID NO: 6, wherein the compound causes an increase (or decrease) in the level of inward chloride current or inositol phosphate release. The Examiner further acknowledged that the specification outlines art-recognized procedures for measuring other activities, but alleged that this is not adequate guidance as to the nature of the activities that may be measured. The Examiner then concluded that undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

In response, in an attempt to advance the prosecution of the captioned application but without conceding either the correctness of the Examiner's position or the need for amendment, Applicants have amended claims 183, 184 and 190 to recite "NPFF receptor activation".

Applicants maintain that that the phrase "receptor activation" is well known to the skilled artisan. In light of the disclosure which teaches a receptor belonging to the class of G-protein coupled receptors (GPCRs), "receptor activation" refers to the activation of a

Christophe P.G. Gerald, et al.
Serial No.: 09/866,248
Filed: May 25, 2001
Page 13

second messenger system within a cell.

See the "Background of the Invention" on page 1 of the instant specification which recites "G-protein coupled receptors (GPCRs) represent a major class of cell surface receptors with which many neurotransmitters interact to mediate their effects. GPCRs are characterized by seven membrane-spanning domains and are coupled to their effectors via G-proteins linking receptor activation with intracellular biochemical sequelae...".

Applicants maintain that intracellular biochemicals are measured by second messenger assays known to those of ordinary skill in the relevant art. Applicants maintain that one would know how to practice the invention based on the instant claims and the many examples of second messenger assays described in the specification.

MPEP §2164.08 recites:

"Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970). One does not look to the claims but to the specification to find out how to practice the claimed invention."

Applicants maintain that claims 183-191, as amended, are enabled under 35 U.S.C. 112, first paragraph and respectfully request that the Examiner reconsider and withdraw this rejection.

Rejection Under 35 USC § 112, Second Paragraph

On page 4 of the March 24, 2005 Office Action, the Examiner rejected claims 183-191

Christophe P.G. Gerald, et al.
Serial No.: 09/866,248
Filed: May 25, 2001
Page 14

under 35 USC 112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter the application regards as the invention.

The Examiner specifically alleged that claims 183-191 are vague and indefinite in the recitation of the term "NPFF receptor activity". In response, in an attempt to advance the prosecution of the captioned application but without conceding either the correctness of the Examiner's position or the need for amendment, Applicants have amended claims 183, 184 and 190 to recite "NPFF receptor activation". Applicants maintain that the phrase "receptor activation" is a term well known to the skilled artisan in the field of G coupled-protein receptors (GPCRs) as discussed hereinabove with respect to the rejection under 35 USC 112, first paragraph.

The Examiner further alleged that there is insufficient antecedent basis for the limitation "the first" in subsection (a) of claim 186. In response, in an attempt to advance the prosecution of the captioned application but without conceding either the correctness of the Examiner's position or the need for amendment, Applicants have amended claim 186 to recite "a first".

The Examiner also rejected claim 186 under 35 U.S.C. 112, second paragraph, for allegedly being incomplete for omitting essential steps. In response, in an attempt to advance the prosecution of the captioned application but without conceding either the correctness of the Examiner's position or the need for amendment, Applicants have amended claim 186 to recite "wherein the second chemical compound is known to bind a mammalian NPFF receptor".

The Examiner further alleged that there is insufficient antecedent basis for the limitation "the mammalian NPFF receptor" in subsection (a) of claims 183-191. In response, Applicants note that the first two lines of subsection (a) of claim 183-191 each recite "a

Christophe P.G. Gerald, et al.
Serial No.: 09/866,248
Filed: May 25, 2001
Page 15

mammalian NPFF receptor" when the term is first introduced. It is only in later repetitions of the claim that the term "the mammalian NPFF receptor" is utilized. Accordingly, applicants respectfully request that this portion of the rejection be withdrawn.

Accordingly, Applicants maintain that the aforementioned amendments and remarks obviate the rejection under 35 U.S.C. 112, second paragraph, and respectfully request that the rejection be withdrawn.

Information Disclosure Statements

In a January 4, 2005 teleconference with Examiner Murphy, the fact that Applicants have not received an initialed version of the PTO-1449 forms corresponding to the Information Disclosure Statements filed on May 25, 2001 (1 page) and July 9, 2001 (1 page) was discussed. The Examiner assured Applicants that the references had been considered and made of record and that the initialed PTO-1449 forms will be sent with the next communication.

Applicants note that the initialed PTO-1449 Forms have still not been returned to Applicants. In order to expedite the prosecution of the captioned application, we have downloaded a copy of each of the PTO-1449 forms referenced above. It is requested that the Examiner consider the above information and that a copy of each of the enclosed Forms be initialed and returned indicating that such information has been considered. Applications respectfully request that the Examiner make the cited references of record in the subject application.

Christophe P.G. Gerald, et al.
Serial No.: 09/866,248
Filed: May 25, 2001
Page 16

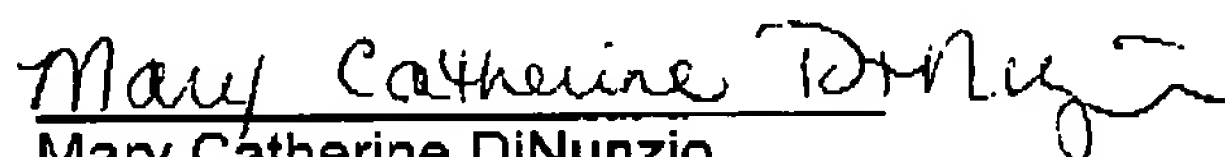
Summary

In view of the foregoing amendments and remarks, Applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone the number provided below.

No fee, other than the fee for a two-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 50-3201.

Respectfully submitted,


Mary Catherine DiNunzio
Registration No. 37,306
Lundbeck Research USA, Inc.
215 College Road
Paramus, New Jersey 07652
(201) 261-1331 (phone)
(201) 986-9106 (fax)